Practitioner's Docket No. 397037 ***PATENT***

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Jordan et al.	)	
	)	
Application No.: 09/021,421	)	Group No.: 1614
	)	
Filed: February 10, 1998	)	Examiner: Cook, R.
	)	
For: CHELATED 8-HYDROXYQUINOLINE AND USE THEREOF IN A METHOD OF TREATING EPITHELIAL LESIONS	)	

DECLARATION OF CARL HANSON

1. My name is Carl Hanson and I am named as an inventor in the present application. I hold an interest in the assignee of my application, Dermex Pharmaceuticals.

2. This Declaration is being provided under 37 C.F.R. 1.132 to provide additional information that the Examiner may think is particularly relevant to patentability.

3. My undergraduate degree is a Bachelor of Science in Pharmacy from the University of Minnesota, which I obtained in 1956. I have done postgraduate work in nuclear pharmacy, and have worked for Abbot Laboratories in that capacity. At present I am semi-retired and do some formulation work in the field of geriatric compositions for Kaiser Permanente. I do other formulations for health and beauty aids that are sold in health food stores.

4. I prepared a first solution (Test 1) to include 10% 8-hydroxyquinoline and 20% zinc chloride by weight according to the following ingredients:

8-hydroxyquinoline sulfate	10 g
$ZnCl_2$	20 g
Purified Water	10 ml
Aquabase (a gel carrier; q.s.)	100 g

5. I prepared a second solution (Test 2) to include 10% 8-hydroxyquinoline and 20% zinc chloride by weight according to the following ingredients:

8-hydroxyquinoline	10 g
$ZnCl_2$	40 g
DMSO	5 ml
Purified Water	10 ml
Plasticized base (a gel carrier; q.s.)	100 g

6. I sent the samples Test 1 and Test 2 to a colleague in veterinary medicine. We selected a test subject—Yoda—a ten year old cocker spaniel with eosinophilic inflammation in both ears. This type of inflammation is poorly understood and is characterized by a granular leukocyte with a nucleus with two lobes. Some of these inflammations develop into cancers and others do not. The test subject had tumor-like growths or lesions on the ears. It is difficult to treat this condition, which is commonly thought to have a possible allergic origin.

7. Test 1 was applied to the left ear of the test subject and Test 2 was applied to the right ear. Test 1 had no apparent effect on the lesion, which remained uncured.

8. Test 2 caused the lesion on the right ear to dry up, and after a few days there was soughing of tissue from the lesion site, which healed nicely. The lesion was cured.

9. It is to be noted that although Test 2 contained 40% by weight $ZnCl_2$, the composition had no escharotic effect on healthy tissue. This means that there was eventual necrosis and sloughing of the lesion, but not in the healthy tissue surrounding the lesion. In my opinion, this is because the presence of 8-hydroxyquinoline alters the formulation balance in a way that the usual 35% escharotic limit may be exceeded.

10. The comparison between Test 1 and Test 2 shows that the use of 8-hydroxyquinoline sulfate is not effective against these lesions. Although the amounts of ZnCl2 differed between Test 1 and Test 2, experience has shown in

other formulations that a 20% formulation is just as effective as a 40% formulation in this regard, as to other lesion types. We are in the process of running a 20% to 20% comparison, but must await the selection of another test subject.

10. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

By: Carl C. Hansen Ph.D.

Carl C. Hansen